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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,012	05/29/2001	Chaitan Khosla	300622000212	9415

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MORRISON & FOERSTER LLP  
3811 VALLEY CENTRE DRIVE  
SUITE 500  
SAN DIEGO, CA 92130-2332

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/870,012	<b>Applicant(s)</b> KHOSLA ET AL.	
	<b>Examiner</b> Kathleen M Kerr	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 8/27/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/27/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action on the merits, a Final rejection (mailed on February 18, 2004), Applicant filed an after-final amendment on June 28, 2004, previously not entered (see Advisory action mailed July 22, 2004), now entered upon receipt of an RCE on August 17, 2004. Said amendment amended Claims 19 and 24 and cancelled Claim 18. Thus, Claims 19 and 24 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/003,338 filed on July 6, 1995 and the U.S. non-Provisional Application No. 08/675,817 (now USPN 6,080,555) filed on July 5, 1996. Neither of these applications, however, disclosed the claimed invention of Claims 19 and 24.

The instant application is granted the benefit of priority for the U.S. non-Provisional Application No. 08/896,323 (USPN 6,066,721) filed on July 17, 1997 and the U.S. non-Provisional Application No. 08/434,289 (now USPN 6,261,816) filed on November 5, 1999. These applications do disclose the claimed invention. Thus, the earliest effective filing date of the claimed invention is considered to be July 17, 1997.

### ***Information Disclosure Statement***

3. The information disclosure statement filed on August 27, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

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***Withdrawn - Claim Objections***

4. Previous objection to Claim 19 for a misspelling is withdrawn by virtue of Applicant's amendment.

***New - Claim Objections***

5. Claim 19 is objected to for a misspelling. "6-deoxyethronolide" should be ---6-deoxyerythronolide---. Correction is required.

6. Claim 24 is objected to for improper grammar. No article precedes "substituent"; ---said-- or ---the--- is required.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

7. Previous rejection of Claims 19 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation "6-dEB" is withdrawn by virtue of Applicant's amendment inserting the full, unabbreviated name into the claims.

8. Previous rejection of Claims 19 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "6-dEB derivative produced in a recombinant organism other than *Saccharopolyspora erythraea*" is withdrawn by virtue of Applicant's amendment.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

9. Previous rejection of Claims 19 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "modified 6-dEB" (formerly 6-dEB derivative) is maintained and amended below. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

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Applicant argues that the claim language is clear and supported in the original specification on page 8, line 5. This is not found persuasive. Said line reads “an experiment to determine whether the post-PKS enzymes in the erythromycin biosynthetic pathway might also accept unnatural substrates”, which neither defines a modified 6-dEB nor speaks to support (this issue is treated below under new matter).

The claim now reads “method to prepare a glycosylated form of a modified 6-dEB wherein said modified 6-dEB **contains** a substituent other than a methyl or ethyl at position 13” (emphasis added). Thus, the scope of “a modified 6-dEB” implies it can be virtually anything provided it has the core 6-dEB structure and not a methyl or ethyl at position 13. However, the specification does not indicate such breadth, nor does Applicant argue such breadth. Thus, the claim language is confusing as to its metes and bounds.

10. Previous rejection of Claims 19 and 24 under 35 U.S.C. § 112, first paragraph, new matter, is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues “It is believed that a skilled artisan reading the specification would understand that 6-dEB forms that lack glycosylation and which have unnatural substituents at position 13 would be included within the scope of the invention.” This is not found persuasive because the claim and its scope must have clear support in the specification as originally filed, not implied support based on inferences from the art.

As previously noted, the instant claims gather their support *only* from Example 4 as originally filed; the remainder of the specification teaches invention(s) wholly distinct from the invention of Example 4, in particular using modified PKS genes (no modification of genes is

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found in the instant claims or in Example 4). Generic mention of “unnatural substrates” being accepted by post-PKS enzymes is noted on page 8, line 5; this reference does not support the genus because modified 6-dEB compounds are not particularly described. Generic mention of “glycosylations at C3 and C5” are also noted at line 7; this reference also does not support the genus because modified 6-dEB compounds are not particularly described nor are non-native compounds whatsoever.

Experimentally in Example 4, mutant *S. erythraea* A34 is fed 6-dEB (compound 1) and makes an unnamed antibiotic (presumably compound 9 on Figure 3), and A34 is then fed compounds 6 and 7 and produces compounds 10 and 11, respectively, as evidenced after extraction. While this experiment supports the conclusion that *S. erythraea* may be able to glycosylate various derivatives of 6-dEB, such a conclusion is never stated. There is no support in Example 4 for the following concepts (breadth) found in the claims:

- a) using *any* modified 6-dEB in the “adding” step - only adding compounds 1, 6, and 7 are supported, and
- b) using any *S. erythraea*, only the A34 strain is supported.

#### ***Summary of Pending Issues***

11. The following is a summary of the issues pending in the instant application:

- a) Claim 19 stands objected to for a misspelling.
- b) Claim 24 stands objected to for improper grammar.
- c) Claims 19 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “modified 6-dEB”.
- d) Claims 19 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.

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*Conclusion*

12. No claims are allowed for the reasons identified in the numbered sections of this Office action for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is **non-final**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

October 20, 2004